

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Khan et. al.

**Serial No.:** To be assigned

**Filed:** April 8, 2004

**For:** METHODS AND USES FOR  
PORTEIN BREAKDOWN PRODUCTS

**Examiner:** To be assigned

**Group Art Unit:** To be assigned

**Attorney Docket No.:** 3077-6384US

**NOTICE OF EXPRESS MAILING**

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Person making Deposit: Christopher Haughton

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 or PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a). Copies of U.S. patents are not being submitted pursuant to Pre-OG Notices <<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/idswouscopies.htm>> (visited 9/15/2003). Copies of foreign patent documents and non-patent literature are enclosed pursuant to 37 C.F.R. § 1.98(a)(2).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in

37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#US- 4,977,244	12-11-1990	Muchmore et al.
US- 5,380,668	01-10-1995	Herron
#US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.
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#US- 6,620,416 B1	09-16-2003	Gallo et al.
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Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#WO 99/59617	11-25-1999	Erasmus Universiteit

#WO 97/49721	12-31-1997	University of Maryland
#WO 01/10907 A2	02-15-2001	University of Maryland
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#97/49373	12-31-1997	University of Maryland Biotechnology Institute
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#FRIEDLANDER, Tackling anthrax, *Nature*, November 8, 2001, pp. 160-61, Vol. 414.

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#LAND et al., "Induction of apoptosis in Kaposi's sarcoma spindle cell cultures by the subunits of human chorionic gonadotropin", *AIDS* 1997, Vol. 11, No. 11, pp.1333-1340.

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#ROHRIG et al., Growth-stimulating Influence of Human Chorionic Gonadotropin (hCG) on *Plasmodium falciparum* in vitro, *Zentralblatt Bakt*, 1999, pp. 89-99, Vol. 289.

#TAK et al., NF-kappaB: a key role in inflammatory diseases, *J Clin Invest.*, 2001, pp. 7-11, Vol. 107.

#TAN et al., The role of activation of nuclear factor-kappa B of rat brain in the pathogenesis of experimental allergic encephalomyelitis, *Acta Physiol Sinica*, 2003, pp. 58-64, Vol. 55.

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#ALBINI, A., et al., "Old drugs as novel angiogenesis inhibitors: Preclinical studies with NAC, hCG, EGCG and somatostatin," 17 *CLINICAL & EXPERIMENTAL METASTASIS* 739 (1999).

#BLACKWELL, Timothy S., et al., "The Role of Nuclear Factor-kB in Cytokine Gene Regulation," 17 *AM. J. RESPIR. CELL MOL. BIOL.* 3-9 (1997).

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#YAMAMOTO, Y., et al., "Role of the NF- $\kappa$ B Pathway in the Pathogenesis of Human Disease States," 1(3) CURRENT MOLECULAR MEDICINE 287-296 (July 2001).

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 10/753,510

Filed: January 7, 2004

For: IMMUNOREGULATORY COMPOSITIONS, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, Applicants offer hereby identifies the following listed copending applications naming the same inventor(s):

**Attorney Docket No.: 3077-6384US**

Attorney Docket No.: 2183-4618US  
Serial No.: 09/716,777  
Filing Date: 11/20/2000  
Title: IMMUNOREGULATOR

Attorney Docket No.: 2183-4799US  
Serial No.: 09/821,380  
Filing Date: 3/29/2001  
Title: IMMUNOREGULATOR

Attorney Docket No.: 2183-5223US  
Serial No.: 10/028,075  
Filing Date: 12/21/2001  
Title: GENE REGULATOR

Attorney Docket No.: 2183-5222US  
Serial No.: 10/029,206  
Filing Date: 12/21/2001  
Title: OLIGOPEPTIDE TREATMENT OF ANTHRAX

Attorney Docket No.: 2183-5526US  
Serial No.: 10/262,522  
Filing Date: 9/30/2002  
Title: IMMUNOREGULATOR

Attorney Docket No.: 3077-5951US  
Serial No.: 10/409,027  
Filing Date: 4/8/2003  
Title: TREATMENT OF TRANSPLANT SURVIVAL

Attorney Docket No.: 3077-5952US  
Serial No.: 10/409,032  
Filing Date: 4/8/2003  
Title: TREATMENT OF TRAUMA

Attorney Docket No.: 3077-5953US  
Serial No.: 10/409,630  
Filing Date: 4/8/2003  
Title: TREATMENT OF MULTIPLE SCLEROSIS

**Attorney Docket No.: 3077-6384US**

Attorney Docket No.: 3077-5957US  
Serial No.: 10/409,642  
Filing Date: 4/8/2003  
Title: TREATMENT OF ISCHEMIC EVENTS

Attorney Docket No.: 3077-5958US  
Serial No.: 10/409,654  
Filing Date: 4/8/2003  
Title: TREATMENT OF NEUROLOGICAL DISORDERS

Attorney Docket No.: 3077-5960US  
Serial No.: 10/409,657  
Filing Date: 4/8/2003  
Title: STRATIFICATION

Attorney Docket No.: 3077-5956US  
Serial No.: 10/409,659  
Filing Date: 4/8/2003  
Title: PEPTIDE COMPOSITIONS

Attorney Docket No.: 3077-5959US  
Serial No.: 10/409,668  
Filing Date: 4/8/2003  
Title: ADMINISTRATION OF GENE-REGULATORY PEPTIDES

Attorney Docket No.: 3077-5955US  
Serial No.: 10/409,671  
Filing Date: 4/8/2003  
Title: TREATMENT OF IATROGENIC DISEASE

Attorney Docket No.: 3077-5954US  
Serial No.: 10/409,694  
Filing Date: 4/8/2003  
Title: TREATMENT OF BURNS

Attorney Docket No.: 3077-4618.1US  
Serial No.: 10/678,995  
Filing Date: 10/3/2003  
Title: IMMUNOREGULATOR

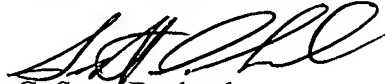
**Attorney Docket No.: 3077-6384US**

Attorney Docket No.: 3077-6084US  
Serial No.: 10/753,510  
Filing Date: 1/7/2004  
Title: IMMUNOREGULATORY COMPOSITIONS

Attorney Docket No.: 3077-6420US  
Serial No.: To be assigned  
Filing Date: April 8, 2004  
Title: COMPOSITIONS CAPABLE OF REDUCING ELEVATED  
BLOOD UREA CONCENTRATION

This Information Disclosure Statement is filed within three (3) months of the filing date of the above-identified application, and no certification pursuant to 37 C.F.R. § 1.97(c) or a fee pursuant to 37 C.F.R. § 1.17(p) is required.

Respectfully submitted,



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Date: April 8, 2004  
ACT/bv  
Enclosures: Form PTO/SB/08

Document in ProLaw



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

1

of

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**Complete if Known**

Application Number	To be assigned
Filing Date	April 8, 2004
First Named Inventor	Khan et. al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	3077-6420US

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		#US- 4,977,244	12-11-1990	Muchmore et al.	
		US- 5,380,668	01-10-1995	Herron	
		#US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.	
		#US- 5,851,997	12-22-1998	Harris	
		#US- 5,877,148	03-02-1999	Lunardi-Iskandar et al.	
		#US- 5,958,413	09-28-1999	Anagnostopoulos et al.	
		#US- 5,968,513	10-19-1999	Gallo et al.	
		#US- 5,997,871	12-07-1999	Gallo et al.	
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		#US- 2002/0064501	05-30-2002	Khan et al.	
		#US- 6,489,296	12-03-2002	Grinnell et al.	
		#US- 2003/0049273 A1	03-13-2003	Gallo et al.	
		#US- 2003/0113733 A1	6-19-2003	Khan et al.	
		#US- 6,583,109 B1	06-24-2003	Gallo et al.	
		#US- 2003/0119720 A1	6-26-2003	Khan et al.	
		#US- 6,596,688 B1	07-22-2003	Gallo et al.	
		#US- 6,620,416 B1	09-16-2003	Gallo et al.	
		US- 2003/186244 A1	10-02-2003	Margus et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		#WO 99/59617	11-25-1999	Erasmus Universiteit		
		#WO 97/49721	12-31-1997	University of Maryland		
		#WO 01/10907 A2	02-15-2001	University of Maryland		
		#WO 01/11048 A2	02-15-2001	University of Maryland		
		#WO 01/72831	10-04-2001	Erasmus Universiteit		
		#2 706 772	12-30-1994	Vacsyn		
		#EP 1 138 692 A1	10/04/2001	Erasmus Universiteit Rotterdam		

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT***(use as many sheets as necessary)*

Sheet

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**Complete if Known**

Application Number	To be assigned
Filing Date	April 8, 2004
First Named Inventor	Khan et. al.
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		Number - Kind Code <sup>2</sup> (if known)			
		US- 5,966,712	10-12-1999	Sabatini et al.	
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				April 8, 2004	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		#EP 1 300 418	04-09-2003	Erasmus Universiteit Rotterdam		
		#WO 98/35691	08-20-1998	Proscript, Inc.		
		#WO 02/085117	10-31-2002	Eisai Co., Ltd.		
		#DE 3715662	11-19-1987	The Wellcome Foundation Ltd.		
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		#96/04008	02-15-1996	Government of the United States		
		#97/49373	12-31-1997	University of Maryland Biotechnology Institute		
		#97/49418	12-31-1997	University of Maryland Biotechnology Institute		
		#97/49432	12-31-1997	University of Maryland Biotechnology Institute		
		WO 03/029292 A2	04-10-2003	Erasmus Universiteit Rotterdam		

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet 3 of 4

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**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		#CONNELLY et al., Biphasic Regulation of NF-kB Activity Underlies the Pro- and Anti-Inflammatory Actions of Nitric Oxide, The Journal of Immunology, 2001, pp. 3873-81, 166, The American Association of Immunologists, USA.	
		#FRIEDLANDER, Tackling anthrax, Nature, November 8, 2001, pp. 160-61, Vol. 414.	
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		#LANG et al., "Induction of apoptosis in Kaposi's sarcoma spindle cell cultures by the subunits of human chorionic gonadotropin", AIDS 1997, Vol. 11, No. 11, pp.1333-1340.	
		#ISKANDAR et al., "Effects of a urinary factor from women in early pregnancy on HIV-1. SIV and associated disease", Nature Medicine, April 1998, Vol. 4, No. 4, pp. 428-434.	
		#CHRISTMAN et al., Nuclear factor kappaB: a pivotal role in the systemic inflammatory response syndrome and new target for therapy, Intens Care Med, 1998, pp. 1131-38, Vol. 24.	
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		#TAK et al., NF-kappaB: a key role in inflammatory diseases, J Clin Invest., 2001, pp. 7-11, Vol. 107.	
		#TAN et al., The role of activation of nuclear factor-kappa B of rat brain in the pathogenesis of experimental allergic encephalomyelitis, Acta Physiol Sinica, 2003, pp. 58-64, Vol. 55.	
		#TOVEY et al., Mucosal Cytokine Therapy: Marked Antiviral and Antitumor Activity, J. Interferon Cytokine Res., 1999, pp. 911-21, Vol. 19.	

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<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Attorney Docket Number	3077-6420US

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		#ALBINI, A., et al., "Old drugs as novel angiogenesis inhibitors: Preclinical studies with NAC, hCG, EGCG and somatostatin," 17 CLINICAL & EXPERIMENTAL METASTASIS 739 (1999).	
		#BLACKWELL, Timothy S., et al., "The Role of Nuclear Factor-kB in Cytokine Gene Regulation," 17 AM. J. RESPIR. CELL MOL. BIOL. 3-9 (1997).	
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Examiner  
SignatureDate  
Considered#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

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For: IMMUNOREGULATORY COMPOSITIONS, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

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